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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 09/403,625 | 02/07/2000 | WINOK DEBYSER | 550-392 | 7510 |
| 23117 | 7590 | 11/17/2003 | EXAMINER | |
| NIXON & VANDERHYE, PC | | | FRONDA, CHRISTIAN L | |
| 1100 N GLEBE ROAD | | | ART UNIT | PAPER NUMBER |
| 8TH FLOOR | | | | |
| ARLINGTON, VA 22201-4714 | | | 1652 | |

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/403,625 | DEBYSER ET AL. |
| | Examiner | Art Unit |
| | Christian L Fronda | 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 48-57 and 65-68 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 48-50,52-56 and 65-68 is/are rejected.
- 7) Claim(s) 51 and 57 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION

1. Claims 48-57 and 65-68 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 48-50, 52-56 and 65-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 8/29/2003 (Paper No. 22) have been fully considered but they are not persuasive. Applicants' position is that the claims as amended recites eight characteristics that is sufficient and that recitation of SEQ ID NO: 2 is not required. The Examiner disagrees with Applicants' position for reasons of record and for the reasons stated below.

The specification only describes a xylanase inhibitor which is a water-soluble, alkaline protein or glycoprotein comprising the amino acid sequences of SEQ ID NO: 1 and SEQ ID NO: 2, a molecular weight of 40-43 kDa, and pI of greater than about 7.0. The claims are directed to any xylanase inhibitor which is a water-soluble, alkaline protein or glycoprotein comprising the amino acid sequence of SEQ ID NO: 1 a molecular weight of 40-43 kDa, and pI of greater than about 7.0.

The specification fails to provide a written description of a genus or class of the claimed proteins or glycoproteins which is expected to be highly variant other than the inhibitor comprising the amino acid sequences of SEQ ID NO: 1 and SEQ ID NO: 2 which is a water-soluble, alkaline protein or glycoprotein with a molecular weight of 40-43 kDa and pI of greater than about 7.0. Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Amending the claims to recite that the claimed inhibitor is a water-soluble, alkaline protein alkaline protein or glycoprotein comprising the amino acid sequence of SEQ ID NO: 1

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and SEQ ID NO: 2, the molecular weight of 40-43 kDa, and pI of greater than about 7.0 may overcome the rejection.

4. Claims 48-50, 52-56 and 65-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for xylanase inhibitor which is a water-soluble, alkaline protein or glycoprotein comprising the amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2, a molecular weight of 40-43 kDa, and pI of greater than about 7.0, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches a xylanase inhibitor which is a water-soluble, alkaline protein or glycoprotein comprising the amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2, a molecular weight of 40-43 kDa, and pI of greater than about 7.0. The nature and breadth of the claims encompass any glycoprotein or protein xylanase inhibitor having any amino acid sequence containing a partial N-terminal sequence of SEQ ID NO: 1 with a pI of greater than 7.0 and a molecular weight of 40-43 kDa. Knowledge regarding the specific structure of the claimed protein or glycoprotein is lacking.

The amount of experimentation to make the claimed inventions is enormous. Such experimentation entails screening vast numbers of organisms for any protein or glycoprotein having any structure and partial N-terminal amino acid sequence of SEQ ID NO: 1 with a pI of greater than 7.0 and a molecular weight of 40-43 kDa and determining whether the protein or glycoprotein is still able to inhibit xylanase enzyme activity. Since routine experimentation does not include screening vast numbers of organisms for a specific organism which contains the claimed protein or glycoprotein which is able to inhibit xylanase enzyme activity, where the expectation of identifying any of the claimed protein or glycoprotein inhibitor is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as the specific amino acid sequence of the claimed protein or glycoprotein. Without such a guidance, the experimentation left to those skilled in the art is undue.

Amending the claims to recite that the claimed inhibitor is a water-soluble, alkaline protein alkaline protein or glycoprotein comprising the amino acid sequence of SEQ ID NO: 1 and SEQ ID NO: 2, the molecular weight of 40-43 kDa, and pI of greater than about 7.0 may overcome the rejection.

Conclusion

5. No claim is allowed.

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6. Claims 51 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



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